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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,990	01/03/2002	Vijay Sharma	RELIA P-106	7830

30294 7590 07/03/2003

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EXAMINER

WORTMAN, DONNA C

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Applicati n No.

10/037,990

Applicant(s)

SHARMA ET AL.

Examiner

Donna C. Wortman, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 20 June 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: Please see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 26-38.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
Donna C. Wortman, Ph.D.  
Primary Examiner  
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Applicant's proposed amendment after final submitted 20 June 2003 as Paper No. 10 has not been entered because it raises issues that would require further consideration and/or search, including an issue of new matter. In particular, regarding the proposed amendment of claims 26, 28, 30, and 38 to recite "forward" and "reverse," Applicant has not pointed out support in the specification as filed for changing "first" to "forward" and "second" to "reverse." Further, if "first" is the same as "forward" and "second" is the same as "reverse," changing the claim language would appear to be unnecessary. If the word meanings are different, the change raises the issue of new matter, and represents an issue that would require further consideration and possibly a new search. Further, Applicant proposes to change the meaning of "amplification component" in the claims, since "amplification component" previously consisted essentially of reagents for amplifying nucleic acids and did not include the primers. Applicant has not pointed out support for the term "detection component," which has not appeared in the claims before. All these proposed changes raise the issue of new matter and represent issues that would require further consideration and possibly a new search.

Applicant has argued that the final rejection was premature because not all the elements of the present claims were addressed and, in particular, alleges that the claimed element "whereby the presence of HCV ... is confirmed by the color of the detection solution ..." was not mentioned.

This argument has been considered but not found persuasive. The first Office action cited Resnick et al. as disclosing that "assay conditions, reagents,

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amounts, and labels are conventional and well-known" (Paper No. 6, page 6, lines 3-5) as well as "kits, reagents, and assay formats for performing such detection assays and teaches the use of probes, preferably labeled ..." (Paper No. 6, page 6, lines 11-13). The rejection over Resnick et al. was repeated in the final Office action and applied to the claims present in the case at that time. Applicant has not pointed out how detection using the presence of color could be unobvious over the use of conventional labels for detection as disclosed by Resnick and set out in the first Office action. Further, if Applicant believed that the presence of color in the detection solution distinguishes over the prior art of record and wished to rely on that argument, Applicant had ample opportunity to present the argument in the response to the first Office action. Finality is not withdrawn.

If the amendment after final had been entered, the amendment to claim 38 would have overcome the objection to claim 38 and the rejection of claim 38 under 35 USC 112, second paragraph.

With respect to the rejection of claims under 35 USC 103(a) over Resnick in view of Geiger, Applicant has argued (1) that there is no motivation for combining the references; (2) that even if combined, the combination does not provide the features of the claimed invention; (3) that the Examiner has misinterpreted Resnick since Resnick teaches probes specific for detecting the C-9 isolate of HCV, so that one of skill in the art would not be motivated to substitute Geiger's probe which is not specific for C-9; (4) that neither of the references mentions "color" as a feature of the invention; (5) that Geiger does not

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teach use of the disclosed probe in the Resnick method, and that use of the probe that Resnick suggests would require experimentation; and (6) that the selections from the two references are made in the light and teaching of Applicant's disclosure.

These arguments have been considered but not found persuasive.

Addressing point (1), both references are concerned with amplification and detection of HCV nucleic acid, and are properly combined; Resnick clearly teaches that a probe is to be selected interior to the pair of primers used, and Resnick discloses a primer pair identical to Applicant's primer pair. With respect to point (2), Resnick teaches the same primer pair as that claimed, along with disclosure of the use of conventional reagents and labels for amplification and detection, and Geiger teaches use of the same probe as Applicant's probe to detect HCV. Addressing point (3), it is apparent that Resnick discloses two separate amplification/detection reactions for HCV nucleic acid, one for sequences that are conserved in several isolates, and one for isolate C9, with the requisite primers and probes for each. Tables 1 and 2 are primers and probes disclosed as useful for detection of conserved regions of HCV; SEQ ID NO:5, identical to Applicant's SEQ ID NO:1, appears in Table 1 and SEQ ID NO:18, identical to Applicant's SEQ ID NO:2, appears in Table 2. Table 4, to which Applicant makes reference, lists only primers and probes with sequences that are specific for isolate C9 and was not relied upon by the Examiner in making the rejection.

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With respect to point (4), Resnick was previously cited for its teaching of conventional labels; examples of such labels are listed as being detectable by spectroscopic, photochemical, biochemical, immunochemical, or chemical means (see, for example, col. 7, lines 19-45, and col. 23, lines 22-25, especially lines 24-25, "in the presence of a chromogenic or chemiluminescent substrate"). The use of conventional labels clearly includes those that are characterized by the development of color. Addressing points (5) and (6), Resnick teaches that a probe is to be selected interior to the primers, and Geiger teaches that a particular probe selected from that region successfully detects amplified HCV nucleic acid. The necessary teachings were available to one of skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw  
July 1, 2003